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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/549,355 | 07/31/2006 | Colin G. Caro | DEHN 200009US01 | 6723 |

27885 7590 07/19/2010

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| EXAMINER | |
|---|---|
| TANNER, JOCELIN C | |
| ART UNIT | PAPER NUMBER |
| 3731 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 07/19/2010 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/549,355 | CARO ET AL. | |
| | Examiner | Art Unit | |
| | JOCELIN C. TANNER | 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *3-6,9,10,12,13,15-24,28 and 29* is/are pending in the application.

4a) Of the above claim(s) *29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6, 9, 10, 12, 13, 15-24, 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This Office Action is in response to the Amendment filed 30 April 2010. Claims 3-6, 9, 10, 12, 13, 15-24, 28 and 29 are currently pending. The Examiner acknowledges the amendments to claims 3-6, 12 and 24, the cancellation of claims 1, 7, 8, 11, 14 and 25-27 and new claim 29.

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 April 2010 has been entered.

### *Drawings*

2. The drawings were received on 30 April 2010. These drawings are acceptable.

### *Election/Restrictions*

3. Newly submitted claim 29 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 29 is directed toward the method of inserting a stent in a fluid conduit and the original presented invention was directed toward an apparatus. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product can be

practiced with another materially different product that does not require an outer wall having a helical portion or a helical center line that varies along the length of the stent.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 29 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**1. Claims 3-6, 12, 13, 15-19 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713) and in view of Edwin et al. (US Patent No. 6,053,943).**

2. Regarding claims **5, 6 and 12**, Houston et al. discloses a conduit that may be a mesh stent (11) [0025] that appears to be expandable since it is disclosed as being collapsible [0021], however, is not expressly disclosed as being expandable, the stent having an expanded configuration that is substantially free of ribs and having a helical center line and a helix angle of 8º that is within the claimed range of less than or equal to 65º ([0010], [0022], [0050], [0051], Fig. 5). Houston et al. fails to disclose an amplitude having a value less than or equal to 0.7 of the internal diameter of the tubing

and to expressly disclose a stent that is expandable from a collapsed configuration and outer wall portions including helical portions having more of a resistance to extension than adjacent portions of the stent.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing having a helical center line with a claimed value of an amplitude less than or equal to 0.7 of the internal diameter, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Evans et al. teaches a mesh stent having a radially compressed and expanded configuration obtained by self-expansion or a force to the body to cause radial expansion that would include balloon expandable means (column 5, lines 53-60).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of Houston et al. with expansion and collapsing means, as taught by Evans et al., to release and remove the stent during and following the desired treatment.

3. Edwin et al. teaches a graft (10) including a support structure or "helical portion"(26) wherein longitudinal strips are helically wrapped around the exterior of the graft such that when longitudinal and radial expansion occurs the amount of expansion is controlled by the amount of resistance applied upon the graft by the helical portion, thereby causing the portions contacting the helical portions to resist a degree of expansion, wherein upon expansion selectively hardened or weakened regions of the helical portions permit different expansion characteristics such that helical portions and

the portions contacting the graft will have a degree of resistance to expansion as opposed to the adjacent graft regions (column 2, lines 48-65, column 4, lines 10-25, column 8, lines 1-10, 30-60, Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a helical portion to the stent of the combination of Houston et al. and Evans et al., as taught by Edwin et al., to control the longitudinal and radial expansion ratios of the final structurally supported graft (column 4, lines 55-58).

4. Regarding claim **3**, Edwin et al. teach strain relief sections or "helical portions" that may be co-extruded with the graft member such that the helical portions have an increased amount of stent forming material relative to the amount of stent forming material of adjacent portions (column 10, lines 10-20).

5. Regarding claim **4**, Edwin et al. teaches curved or "bent" portions of the helical portions wherein the bent portions remain bent when expanded (Fig. 1).

6. Regarding claim **13**, Houston et al. discloses a helical center line formed by internal ridging that has an amplitude and tubing with an internal diameter. Houston et al. fails to disclose the value of 0.05 calculated by dividing the amplitude of the helical centre line by the internal diameter of the tubing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing with the claimed values found by dividing the amplitude of the helical centre line by the internal diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering

the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

7. Regarding claim **15**, Houston et al. discloses Houston et al. discloses a stent (300) having an expanded configuration with a helical center line and a helix angle of 8° that is within the claimed range of less than or equal to 15° ([0010]).

8. Regarding claim **16**, Houston et al. discloses a stent having a circular cross-section (Fig. 5).

9. Regarding claim **17**, Houston et al. discloses a helical center line of the stent extending over part of the overall length of the stent (Fig. 5).

10. Regarding claim **18**, Houston et al. discloses a helical center line of the stent extending over substantially the entire length of the stent (Fig. 5).

11. Regarding claim **19**, Houston et al. discloses a helical center line following a substantially helical path about a curved axis (Fig. 5).

12. Regarding claim **21**, Houston et al. discloses a helical centre line formed by internal ridging that has an amplitude and tubing with an internal diameter. Houston fails to disclose the value of 0.1 calculated by dividing the amplitude of the helical centre line by the internal diameter of the tubing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing with the claimed values found by dividing the amplitude of the helical centre line by the internal diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering

the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

13. Regarding claim **22**, Houston et al. discloses a stent (11) undergoing a turn of the helix wherein the stent has a helical configuration with at least one helical turn (Fig. 5).

14. Regarding claim **23**, Houston et al. discloses a stent having a helical portion that has the same number of turns in the expanded and collapsed conditions (Fig. 5).

**15. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713) in view of Edwin et al. (US Patent No. 6,053,943), as applied to claim 12 above, and further in view of Inderbitzen et al. (US Patent No. 5,484,411).**

16. Regarding claim **9**, the combination of Houston et al., Evans et al. and Edwin et al. discloses a balloon expandable stent (column 3, lines 2-6, Evans et al.). However, the combination of Houston et al. and Evans et al. fails to disclose a balloon having an expandable wall that resists extension more helical portions of the balloon.

Inderbitzen et al. teaches an expandable balloon used in angioplasty procedures including a longitudinally extending spiral wall (38) extending from the distal to proximal end of the balloon, formed integrally with the exterior surface of the balloon and radially restricting the expansion of the balloon along the longitudinally extending spiral path (column 3, lines 45-53, Fig. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the balloon of the combination of

Houston et al., Evans et al. and Edwin et al., with a helical portion, as taught by Inderbitzen et al., to exhibit a low crossing profile and to avoid the need to rotate the balloon within a vessel to ensure dilation.

17. Regarding claim **10**, Inderbitzen et al. teaches a balloon having an exterior surface or expandable wall wherein the wall thickness is greater in sections include a spiral wall or "helical portion" (38) (Fig. 2).

**18. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713) in view of Edwin et al. (US Patent No. 6,053,943), as applied to claim 12 above, and further in view of Igaki et al. (US Patent No. 5,733,327).**

Regarding claim **20**, the combination of Houston et al., Evans et al. and Edwin et al. discloses all of the limitations previously discussed except for a pharmaceutical coating.

Igaki et al teach coating a stent to provide locally limited and long-term dosage of drugs (column 2, line 51 and column 3, lines 19-22).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent of the combination of Houston et al., Evans et al. and Edwin et al., with the coating or drug induced fiber, as taught by Igaki et al., to provide locally limited and long-term dosage of drugs.

19. **Claims 24 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713) in view of Nunez et al. (6,596,023).**

20. Regarding claim **24**, Houston et al. discloses a conduit that may be a mesh stent (11) [0025] that appears to be expandable since it is disclosed as being collapsible [0021], however, is not expressly disclosed as being expandable, the stent having an expanded configuration that is substantially free of ribs and having a helical center line and a helix angle of 8° that is within the claimed range of less than or equal to 65° ([0010], [0022], [0050], [0051], Fig. 5). Houston et al. fails to disclose an amplitude having a value less than or equal to 0.7 of the internal diameter of the tubing and to expressly disclose a stent that is expandable from a collapsed configuration.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing having a helical center line with a claimed value of an amplitude less than or equal to 0.7 of the internal diameter, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Evans et al. teaches a mesh stent having a radially compressed and expanded configuration (column 5, lines 53-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of Houston et al. with expansion and collapsing means, as taught by Evans et al., to release and remove the stent during and following the desired treatment.

However, the combination of Houston et al. and Evans et al. fails to disclose a conduit having a helical center line that varies along the length of the stent.

Nunez et al. teaches a mesh stent (column 16, lines 22-36) having a helical center line (Fig. 6) wherein the helix angle and/or amplitude of the center line varies or changes from one axis to another along the length of the stent, the helical center line having the capability of introducing a gentle swirl to increase the swirling of the fluid.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of the combination of Houston et al. and Evans et al., with a varying helical center line, as taught by Nunez et al., to avoid the need to customize stents by using sutures (column 3, lines 49-55).

21. Regarding claim **28**, Nunez et al. teaches a stent having a pitch and amplitude that change along the length of the stent (Fig. 7).

22. **Claims 24 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713) in view of Cymbalisty (US Patent No. 6,896,007).**

23. Regarding claim **24**, Houston et al. discloses a conduit that may be a mesh stent (11) [0025] that appears to be expandable since it is disclosed as being collapsible [0021], however, is not expressly disclosed as being expandable, the stent having an expanded configuration that is substantially free of ribs and having a helical center line and a helix angle of 8° that is within the claimed range of less than or equal to 65° ([0010], [0022], [0050], [0051], Fig. 5). Houston et al. fails to disclose an amplitude having a value less than or equal to 0.7 of the internal diameter of the tubing and to expressly disclose a stent that is expandable from a collapsed configuration.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing having a helical center line with a claimed value of an amplitude less than or equal to 0.7 of the internal diameter, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Evans et al. teaches a mesh stent having a radially compressed and expanded configuration (column 5, lines 53-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of Houston et al. with expansion and collapsing means, as taught by Evans et al., to release and remove the stent during and following the desired treatment.

However, the combination of Houston et al. and Evans et al. fails to disclose a conduit having a helical center line having a helix angle and/or amplitude that varies along the length of the stent.

Cymbalisty teaches a conduit having a helical center line (Fig. 5) wherein the helix angle and/or amplitude of the center line varies or changes form from one axis to another along the length of the stent, the helical center line having the capability of introducing a gentle swirl to increase the swirling of the fluid (column 3, lines 28-46).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of the combination of Houston et al. and Evans et al., with a varying helix angle or amplitude, as taught by Cymbalisty, to provide directional flow changes (column 3, lines 12-15).

24. Regarding claim **28**, Cymbalisty teaches having a pitch and amplitude that change along the length of the tubular member and it would have been obvious to apply this to the stent of Houston as discussed above (column 3, lines 28-46).

***Response to Arguments***

25. Applicant's arguments filed 30 April 2010 have been fully considered but they are not persuasive. In response to applicant's argument that Nunez fails to disclose a helical center line having a varying helix angle or amplitude. However, Nunez teaches a stent having a sinusoidal or S-shaped configuration such that the line running through the center of the stent has a spiral or S-shaped form which include changing angles. The Applicant contends that the change in amplitude and pitch can be achieved by increasing or decreasing the resistance to extension provided by helical portion, however, claims 24 and 28 fail to require a helical portion. A rejection of Cymbalisty has been submitted to show a different interpretation of a change in pitch and amplitude. Applicant's arguments with respect to Hogan have been fully considered and are persuasive. The rejection of claims of 3-6, 12, 13, 15-19 and 21-23 has been withdrawn.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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